

**To:** Office of Attorney General  
[AGO.highcostprescriptiondrugs@vermont.gov](mailto:AGO.highcostprescriptiondrugs@vermont.gov)

**From:** Mylan Pharmaceuticals Inc.  
781 Chestnut Ridge Road  
Morgantown, WV 26505

**Date:** July 23, 2021

**Re:** 18 V.S.A § 4637

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In compliance with 18 V.S.A. § 4637, on June 25, 2021 Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced new authorized generic prescription drug, Formoterol Fumarate 20mcg/2mL, Nebulizer Solution, 60 ct. & Formoterol Fumarate 20mcg/2mL, Nebulizer Solution, 30ct., ("the Products"), to the commercial market on June 22, 2021 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Products. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

Mylan reserves the right to reassess reporting requirements under the definition of a "new prescription drug" in any future submissions. This authorized generic Product is marketed under an NDA that was previously approved in 2007 and did not receive an initial approval under an original NDA.

- (1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

*Formoterol Fumarate 20mcg/2mL, Nebulizer Solution is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:*

NDC	Products	Package Size	WAC
00378-1631-91	Formoterol Fumarate 20mcg/2mL, Nebulizer Solution	60	\$962.47
00378-1631-93	Formoterol Fumarate 20mcg/2mL, Nebulizer Solution	30	\$481.26

*The prices negotiated with customers as well as any marketing plans in the United States or internationally are confidential and not in the public domain or publicly available. In the United States, Mylan sells its products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities and mail order pharmacies. Mylan also sells its generic*

*products indirectly to several entities, including independent pharmacies, managed care organizations, hospitals, etc. These customers, called “indirect customers,” purchase our products primarily through our wholesale customers.*

(2) the estimated volume of patients who may be prescribed the drug;

*No information specific to the estimated number of patients that may be prescribed Mylan’s Products is in the public domain or publicly available.*

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

*The Products were not granted breakthrough therapy designation or priority review by the FDA.*

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

*The Products were not the result of a product acquisition.*